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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,455	06/23/2003	Rosenberg Meir	COD5001	9738
27777	7590	03/16/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			DEAK, LESLIE R	
		ART UNIT	PAPER NUMBER	
		3761		
DATE MAILED: 03/16/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,455	MEIR, ROSENBERG	
Examiner	Art Unit		
Leslie R. Deak	3761		

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 25 January 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 January 2006 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on 25 January 2006. These drawings are accepted.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 15-17 and 34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

35 U.S.C. 112, sixth paragraph states that a claim limitation expressed in means-plus- function language "shall be construed to cover the corresponding structure...described in the specification and equivalents thereof." "If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112." See MPEP § 2181, citing In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (in banc).

Applicant has failed to set forth what structure is meant by the "means for being...powered" in claims 15-17 and 34-36. Page 6 of applicant's specification provides a disclosure that the device may be powered by RF, acoustic, or optical waves, but discloses no structure capable of carrying out the powering function. Therefore, the disclosure is not enabling for a "means for being...powered" by the various claimed power sources.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 15-17 and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

- a. the claim limitations must use the phrase "means for " or "step for; "
- b. the "means for " or "step for " must be modified by functional language; and
- c. the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the event that it is unclear whether the claim limitation falls within the scope of 35 U.S.C. 112, sixth paragraph, a rejection under 35 U.S.C. 112, second paragraph may be appropriate.

Claims 15-17 and 34-36 appear to be an attempt to invoke 35 U.S.C. 112, sixth paragraph analysis, but fail since they appear to recite a material or structural limitation for carrying out the “means for being...powered.” By reciting RF, acoustics, and optics in the claim as a part of the “means for being...powered,” applicant recites a limitation that removes the claim from 35 USC 112, 6th paragraph analysis. Therefore, the scope of the claims is unclear, rendering the claims indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 21, 24, and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,585,677 to Cowan, Jr. et al.

In the specification and figures, Cowan discloses the device as claimed by applicant. In particular, Cowan discloses a shunt with catheters 28 and 32, connected by catheter line 34, a master control unit 24 that comprises a valve-gauge assembly 52 with pressure gauges or sensors, a valve to control fluid flow, and a microprocessor that receives and interprets inputs from the pressure gauges to control the valve and fluid flow (see column 5, lines 10-35). Pressure gauge 54 monitors the pressure of fluid in line 34, indicating that it is contained within the housing of catheter line 34. Pressure gauge 54 is upstream of valve 50, and pressure gauges in assembly 52 are located

downstream of valve 50, wherein all the components are within the housing of the catheter and control system disclosed by Cowan. Therefore, the claim reads on the device disclosed by Cowan.

The processing units of the valve-gauge assembly are connected to a transmitter 64 that acts as an antenna to transmit data from the valve-gauge assembly to a wireless receiver and external computing device located proximal to a patient (see column 6, lines 1-15). The external computing device may further process the signals or merely report them in a readable format. Applicant recites claim limitations drawn to the mode of operation of the controller. Such a limitation is regarded as a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Furthermore, it is the position of the examiner that the microprocessor of the Cowan device may be programmed to perform the operations claimed by applicant.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 6-14, 18-20, 22-23, 25-33, 37, and 41-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al.

Cowan discloses the apparatus and method as claimed with the exception of specifically reciting a third and fourth pressure gauge or sensor in the device. Cowan discloses that his device comprises several sensors, including pressure gauges. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add a third and fourth pressure sensor, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. See MPEP § 2144.04. Similarly, mere repetition of the steps in a method is an obvious variation on a method disclosed in the prior art.

With regard to applicant's claims drawn to the location of the CPU or microprocessor inside or outside the housing, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the CPU inside or outside the housing, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP § 2144.04.

With regard to applicant's claim drawn to a differential pressure sensor, such a sensor involves two discrete parts that measure and calculate the difference in pressure in separate locations, much like the separate sensors and microprocessor of the Cowan device operate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the discrete units into a differential pressure sensor, since it has been held that forming in one piece an article what has formerly been formed in multiple pieces and put together involves only routine skill in the art. See MPEP § 2144.04.

With regard to claims 41-46, Cowan discloses that his device may comprise multiple pressure gauges in the valve-gauge assembly 52, therefore placing the multiple pressure sensors within the housing of master control unit 24 and on the same substrate (see column 5, lines 40-45).

10. Claims 15-17 and 34-36, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,585,677 to Cowan, Jr. et al., as applied above, in view of US 6,061,596 to Richmond et al.

In the specification and figures, Cowan discloses the apparatus substantially as claimed by applicant with the exception of a power source comprising RF, acoustics, or optics. Richmond discloses an implanted medical stimulator that uses RF, acoustics, or optics to power the implanted device (see column 8, lines 10-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace the battery disclosed by Cowan with an alternate energy source as disclosed by Richmond, in order to power the implanted device, as taught by Richmond.

Response to Arguments

11. Applicant's amendment filed 25 January 2006 has been entered and considered.
12. Applicant's arguments filed 25 January 2006 have been fully considered but they are not persuasive.
13. Applicant argues that the prior art fails to disclose that the pressure sensors disclosed by Cowan are in the housing of master control unit 24. However, examiner considers the entire catheter assembly (including catheter line 34, connecting inflow

catheter to the master control assembly and outflow catheter) to comprise a housing.

Pressure gauge 54 monitors the pressure of fluid in line 34, indicating that it is contained within the housing of catheter line 34. Pressure gauge 54 is upstream of valve 50, and pressure gauges in assembly 52 are located downstream of valve 50, wherein all the components are within the housing of the catheter and control system disclosed by Cowan. Therefore, the claim reads on the device disclosed by Cowan.

14. Applicant has added "means for" language to include the function of the claimed elements as structural limitations of the device.

15. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis (see MPEP § 2181):

- a. the claim limitations must use the phrase "means for" or "step for;"
- b. the "means for" or "step for" must be modified by functional language; and
- c. the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

15. If the examiner finds that a prior art element:

- a. performs the function specified in the claim,
- b. is not excluded by any explicit definition provided in the specification for an equivalent, and
- c. is an equivalent of the means- (or step-) plus-function limitation,

then the element in the prior art is considered within the scope of applicant's claimed limitation and renders the instantly claimed invention unpatentable.

16. Amended claims 3-5, 9, 10, 14, 26, 30, moer satisfy the three-prong test and will be analyzed under 35 USC § 112, 6th paragraph.

17. With regard to claims 3, 9, 26, and 30, applicant claims a “means for wirelessly communicating” that is disclosed as an antenna 28 on page 4 of the specification. Cowan meets this limitation by disclosing a transmitter 64 that operates wirelessly to emit signals to an external device. The transmitter disclosed by Cowan performs the “wirelessly communicating” function, is not excluded by applicant’s specification, and is an equivalent device to applicant’s antenna. Therefore, Cowan’s disclosure anticipates applicant’s claim 3.

18. With regard to claims 4-5, 10, and 14, applicant claims a “means for calculating” that is disclosed as a processor on page 4 of the specification. Cowan meets this limitation by disclosing processing units of valve-gauge assembly 52 and diagnostic unit 60. The processor disclosed by Cowan performs a calculating function, is not excluded by applicant’s specification, and is equivalent to applicant’s disclosed processor. Therefore, Cowan’s disclosure anticipates applicant’s claims 4-5.

19. In response to applicant’s argument that placing additional pressure sensors is not an obvious variation on the disclosures in the prior art, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the instant case, Cowan discloses pressure sensors located in discrete locations in order to provide pressure measurements from those locations within the

catheter system. Cowan further discloses that the assembly may comprise additional sensors that provide information as to the condition of the patient and the shunt (see column 5, lines 35-48). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide additional sensors to the Cowan shunt, not only since duplication of the essential working parts of a device is within the skill of a worker in the art, but to provide additional measurements as taught by Cowan.

20. Applicant argues that it is not obvious to combine two pressure sensors to create a differential pressure sensor. However, applicant's specification, on page 4, discloses that a differential pressure may be calculated from the differential pressure between the first pressure sensor and the second pressure sensor. Applicant thus discloses that the combination of two pressure sensors may provide an equivalent result as a single differential pressure sensor, rendering such a substitution obvious to a worker of ordinary skill in the art.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

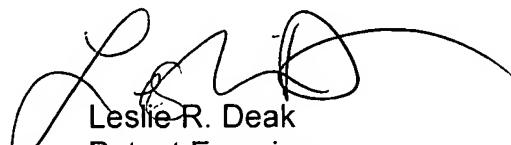
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Leslie R. Deak
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Art Unit 3761
7 March 2006